

July 18, 2011

MEMORANDUM FOR: Chairman Gregory B. Jaczko
Commissioner Kristine L. Svinicki
Commissioner George Apostolakis
Commissioner William D. Magwood, IV
Commissioner William C. Ostendorff

FROM: Peter Crane
Counsel for Special Projects, USNRC (retired)

On July 13, the NRC issued press announcements on two unrelated matters: the public release of the report of the NRC staff's Task Force on the Fukushima accident (news release No. 11-127), and the Commission's directive to the staff "to examine feasibility and need of study on radiation doses to public from nuclear medicine" (news release No. 11-128).

The Task Force report touches on, though only very minimally, the use of potassium iodide (KI) as a thyroid blocking agent; the directive on nuclear medicine relates directly to the issue of the release of patients with high doses of radioactive iodine-131 in their systems. Both as an NRC employee and as a retiree, I have been involved with these two subjects for many years – nearly 30 years, in the case of KI, and almost 20 years, with respect to radioactive patients – and I have considerable institutional knowledge in these areas.¹ I feel obligated to the current Commissioners, the agency, and the public, to share some of this history with them, and explain why the July 13 issuances are problematic. Since I see that the schedule calls for the Task Force to brief the Commission on July 19, I will in the interest of time deal with the first today and the second in a memorandum to be submitted in the near future.

The charter of the NRC staff Task Force on Fukushima was set forth in a March 23, 2011, tasking memorandum from Chairman Jaczko to R. W. Borchardt, the Executive Director for Operations (Appendix B to the report, p. 77), and the March 30, 2011, memorandum from Mr. Borchardt to Martin Virgilio and Charles Miller (Appendix C to the report, p. 79). The Task Force was given the specific task of considering, among other things, "Emergency preparedness (e.g. emergency communications, **radiological protection, emergency planning zones, dose projections and modeling, protective actions**)."² [Emphasis added.]

Protective actions include, as the report acknowledges, potassium iodide. The following seem like obvious questions: How widely was potassium iodide distributed in Japan? How far away from Fukushima did radioactive iodine show up in foodstuffs, water, and air? What kind of radiation doses to the thyroid were received by Japanese citizens, especially children, and at what distances from the reactors? What does this suggest about the need for KI beyond the 10 mile radius in which the NRC now offers it?

These are all questions that can be answered, to a greater or lesser extent, by any informed citizen who reads the newspapers and has access to a computer, but anyone whose only source of information is the NRC Task Force, which was in theory addressing such issues, would be out of luck. Indeed, such a person would not even realize that these issues existed, for the Task Force has tiptoed around them.

The Task Force must surely be aware that the NRC has come under sharp criticism for its role in preventing the implementation of a law, Section 127 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which would have extended the availability of KI out to a 20-mile radius. A January 2008 decision by the President's Science Advisor, Dr. John H. Marburger III, declined to implement that portion of the Act. The Task Force must also know that a bipartisan group of some 30 Members of Congress, including Rep. Ed Markey, the law's sponsor, has called on the President to revisit that decision and authorize the broader stockpiling and distribution of the drug, and that this issue is under reconsideration by the Administration.

But no reader of this report would realize any of that, or find a scintilla of information that might shed light on the question of whether current policy needs revision. What is more, an Associated Press story on March 31, 2011, quoted Patricia Milligan, the NRC's senior expert on KI matters, as saying that the NRC was "absolutely confident" that the 10 mile radius for stockpiling of KI was sufficient. Considering that the accident was still unfolding rapidly at that time, this was highly premature. It was only on March 23, after all, that Chairman Jaczko had directed the staff to examine, among other things, "emergency planning zones" and "protective actions." If the staff had completed its review of the KI issue in the intervening eight days, this was quick work indeed.²

The Marburger decision and the NRC's role in it deserve further discussion here. As the Commission is probably aware, the legislation authorizing the expansion of KI distribution from 10 to 20 miles from nuclear power plants was passed by an overwhelming margin in 2002 and signed into law by President Bush. The White House, in a 2002 statement, hailed the result, say-

ing that henceforth, KI, which it called “crucial” and “critical,” would be available wherever needed, not just within what it termed the “artificial ten-mile barrier.” The Department of Health and Human Services was given the task of implementing the law, which NRC had opposed.

But to begin distribution of KI, which HHS was eager to do, for it saw a plain need to improve protection for America’s children, it was required to publish guidelines. Opponents of the law prevailed on the Office of Management and Budget to withhold its approval of those guidelines, and thereby delay implementation of the law, to the great frustration of HHS.

The same law directed the National Academies of Science to perform a study of KI. Published in 2004 under the title *Distribution and Administration of Potassium Iodide in the Event of a Nuclear Incident*, it made clear, inter alia, that “children are most likely to benefit from KI prophylaxis” (p. 4); that thyroids are at risk in a nuclear incident from “inhalation of contaminated air or ingestion of contaminated food or milk” (p. 3); that “KI should be available to infants, children, and pregnant and lactating women” (p. 5); that though KI distribution to date focused only on the 10-mile Emergency Planning Zone utilized by the NRC, the variation from site to site meant that “no single best solution exists,” and that a specific incident might require KI “beyond the EPZ as well” (p. 161); and that as a result, “**KI distribution programs should consider predistribution, local stockpiling outside the emergency planning zone (EPZ), and national stockpiles and distribution capacity.**” (p. 160, emphasis in the original)

In a November 1, 2005, letter to HHS, the NRC brazenly misrepresented the findings of the NAS report. Writing to Dr. Robert Claypool of HHS, William F. Kane, NRC Deputy Executive Director for Reactor and Preparedness Programs, asserted – purportedly on the basis of the NAS report – that the only pathway of concern beyond the 10-mile radius would be ingestion, which could be controlled by interdiction of foodstuffs, and, in a particularly egregious distortion, declared that “the Academy raised questions about the usefulness of expanded distribution of KI.”³

HHS Secretary Michael Leavitt responded with a letter to NRC Chairman Nils Diaz⁴, dated March 27, 2006, which though couched in superficially civil terms was an acid rebuke that made clear that NRC had quoted snippets of the NAS report out of context to produce a misleading impression. He quoted the actual words of the NAS report back to Diaz: “A specific incident might call for protective actions to be restricted to a small part of the EPZ **or require that they be implemented beyond the EPZ as well,**” boldfacing the last 11 words for emphasis.⁵ Secretary Leavitt’s letter plainly did not faze the NRC, however, which in an April 10, 2006, letter to Senator George Voinovich, responding to questions arising from a recent oversight hearing, re-

peated the assertion that the NAS supported the NRC position on the undesirability of stockpiling KI beyond ten miles, and attached the Kane letter.⁶ (The answer came in response to a question from Sen. Isakson.) By now, there was no excuse for inaccuracy. If the staff had somehow contrived to misread the NAS report at the time it wrote to Dr. Claypool in November 2005, any such misunderstanding had been cleared up by Secretary Leavitt, in his letter of March 27, 2006.

With his declared intention of implementing the law and providing KI in the 10 to 20-mile radius, Secretary Leavitt was on a collision course with the NRC and the nuclear industry. The White House was persuaded to forget or ignore what it had said in 2002 about eliminating the “artificial 10 mile barrier” to the distribution of this “crucial” and “critical” drug. On July 2, 2007, President Bush signed an order that stripped Leavitt of his authority over the law and transferred it to the NRC and to his own Science Advisor, Dr. Marburger, who would have the final say on whether to implement the law.

At Marburger’s request, a technical evaluation paper on KI was prepared by the Potassium Iodide (KI) Subcommittee of the Federal Radiological Preparedness Coordinating Committee (FRPCC), an interagency group. On October 23, 2007, FRPCC Chair Vanessa Quinn, of FEMA, transmitted the paper to Marburger, with a cover letter that made plain the leading role of the NRC staff in the effort.⁷

Marburger’s decision, issued on January 22, 2008, predictably found no need to implement the 2002 law. This is not the place to get into the legal question of whether his refusal to do so was consistent with Congressional intent and a proper reading of the statute, though I have strong views on that point; I would like instead to stay with the technical and policy bases for his decision.

Perhaps the most extraordinary thing about the Marburger decision was that the President’s Science Advisor felt able to issue a 13-page decision on a drug for the prevention of cancer without ever using the word “cancer.” Instead, he referred euphemistically to “adverse thyroid conditions.” From the chief scientist in the United States Government, this defies comprehension. Is it conceivable that any Government official would issue a decision on the use of Sabin vaccine without ever employing the word “polio”? Of course not. But when the subject is KI and thyroid cancer, this happens again and again.⁸

Let us now look at the important question of what exactly Marburger was relying *on*. At p. 12 of his decision, he wrote:

Some concerned citizens groups criticize meteorological analyses that assume a wind that blows constantly in a single direction, suggesting that variable trajectory models would better account for complex wind patterns, leading to accident consequences extending beyond current projections. In fact the opposite is true. The NRC and FEMA outline their strategies for emergency planning in the 2002 study *Assessment of the Use of Potassium Iodide (KI) as a Supplemental Public Protective Action during Severe Reactor Accidents* (NUREG 1633)^{fn}, which addresses the effect of meteorology on accident consequences, specifically its effect on where the offsite release goes....

The footnote included a citation to this document, which states on its cover page that it was “Prepared by P. A. Milligan/NRR.”⁹

What Marburger evidently did not know was that officially, this document was in the dumpster. In November 2002, the Commission had decided, on a 4-1 vote, with Commissioner Dicus the lone dissenter, that it was unfit for publication, and that no more resources should be spent on bringing it up to standard. Commissioners’ comments on it were not gentle. Commissioner McGaffigan noted that although it was the 9/11 attacks that had spurred states’ interest in KI stockpiling, “the draft NUREG is silent on the subject.” Commissioner Diaz wrote:

The draft NUREG now before us is the third version we have been asked to review since mid1998. (The first version was withdrawn by the Commission and we disapproved the second one.) ... In my opinion, it’s time to pull the plug.¹⁰

I do not know where Dr. Marburger got his copy of the draft NUREG – perhaps it was not from the NRC at all – but surely he could and should have been warned by his NRC advisor that the document had been rejected by the Commissioners and therefore had no place in his decision.

Relying as it did on an invalid document, Marburger’s decision must therefore be considered at least partially tainted. Its pernicious effects, moreover, have extended far beyond the question of implementing the 2002 law. After its issuance, the interagency group that maintains the Strategic National Stockpile removed KI from the arsenal of protective drugs that comprise that stockpile, to which it had been added after 9/11.¹¹ I am told that the group felt that it had no choice, in light of the Marburger decision.

At a time at which in every other sphere of life, America is *increasing* its preparedness against terrorism, the NRC has thus been instrumental in *diminishing* our country’s preparedness to deal with acts of nuclear terrorism or other nuclear catastrophes. It must be borne in mind what the

consequences of insufficient preparedness will be, if such a disaster occurs: an increased incidence of thyroid cancer, especially in children who were very young, or still in the womb, at the time of exposure.¹²

I would be the last person to argue that KI is a panacea for protection against radiological disasters. Indeed, in the early days of the Fukushima accident, I went on television in Seattle to say that it would “irresponsible scaremongering” to suggest that anyone in the U.S. should now be taking KI to protect against the releases from Japan. But it is likewise irresponsible in the extreme not to have adequate supplies on hand in this country, for accidents or acts of terrorism occurring here, and of all the possible reasons for failing to stockpile it, protecting the public image of the nuclear power industry is surely the rock-bottom worst.¹³

The real question is whether KI would be useful in the event of a major release, for if not, there is no point in having it, regardless of its low cost. The opponents of KI stockpiling have long maintained that KI is unnecessary, because the whole problem of thyroid protection can be solved by instructing people to refrain from drinking milk after a major nuclear release. For example, in the early days of the Fukushima accident, a March 13 article in the *New York Times* quoted a radiation expert at Columbia, Dr. David Brenner:

Dr. Brenner said the iodine pills were protective, but were “a bit of a myth” because their use is based on the belief that the risk is from inhaling radioactive iodine. Actually, he said, 98 percent of people’s exposure comes from milk and other dairy products.

“The way radioactive iodine gets into human beings is an indirect route,” he said. “It falls to the ground, cows eat it and make milk with radioactive iodine, and you get it from drinking the milk. You get very little from inhaling it. The way to prevent it is just to stop people from drinking the milk.” He said that the epidemic of thyroid cancer around Chernobyl could have been prevented if the government had immediately stopped people from drinking milk.

I have no idea where Dr. Brenner got this 98% figure; most sources I have seen think that 70 or 80 percent of the Chernobyl exposures came from the milk pathway, not more. At any rate, once I-131 began showing up in Tokyo’s tap water, I wrote a letter to the *New York Times*, published on March 26, that was implicitly a slap at Dr. Brenner and the reporter who had so uncritically relied on him.¹⁴

Whether for that reason or some other, Dr. Brenner’s public position on KI changed almost instantaneously. On the afternoon of the same day, March 26, a glowing profile of him, “Counter-

ing Fears With Just the Facts,” was posted on the *New York Times* website (it appeared in print on March 29), which included the following:

Potassium iodide pills are widely recommended to protect the thyroid gland from radioactive iodine, but Dr. Brenner said it was better just to stop drinking milk until the threat had passed.

His message changed, however, when radioactive iodine turned up in tap water in Tokyo. Though the public was advised that babies, children and pregnant women should not drink the water, Dr. Brenner conceded that some exposure might still be hard to avoid, and that using potassium iodide was a reasonable precaution.

“I’ve been maybe a little overstrong in saying that potassium iodide doesn’t have a role to play,” he said. “But usually the problem is milk. To me, the levels in water came as a surprise.”

But is it really a “myth,” as Dr. Brenner suggested in the earlier article, that inhalation of I-131 after a radiological release is a danger?

Nearly 20 years ago, the Environmental Protection Agency issued a “Manual of Protective Action Guides and Protective Actions for Nuclear Incidents,” EPA 400-R-92-001 (May 1992)¹⁵, that included the following, at p. 5-20: “If a major release of radioiodine or respirable particulate materials occurs, **inhalation dose will be the controlling pathway.**” [Emphasis added.] It recommended, among other things, consideration of the use of KI. It made the point that though evacuation in an emergency is the ideal option, you can get a radiation dose while evacuating, and that automobiles offer only about 10% shielding.

The Food and Drug Administration issued guidance on KI in 2001.¹⁶ At p. 8, after noting that the post-Chernobyl exposures to radioiodines came “largely” from the milk pathway, it said:

In this or similar accidents, for those residing in the immediate area of the accident or otherwise directly exposed to the radioactive plume, **inhalation of radioiodines may be a significant contributor to individual and population exposures.** ... The risk depends on factors such as the magnitude and rate of the radioiodine release, wind direction and other atmospheric conditions, and thus may affect people both near and far from the accident site. [Emphasis added.]

There was also a useful report from the International Atomic Energy Agency in 2002.¹⁷ At p. 52, the joint IAEA/WHO committee that prepared it makes the point that “iodine prophylaxis is in-

tended **primarily as a protective action against inhalation,**” in the short term, and suggests amending the International Basic Safety Standards to reflect this. [Emphasis added.]

In 2003, the Medical Preparedness and Response Sub-Group of the Department of Homeland Security Working Group on Radiological Dispersal Device Preparedness prepared a report saying that if terrorists detonated a radiological dispersal device containing radioiodine or a 10-kiloton improvised nuclear weapon, millions of doses of KI might be needed to deal with the fallout. It said, at p. 62: “Urgent consideration for giving KI to pregnant women (especially 2nd and 3rd trimesters) and children is appropriate.”¹⁸

On June 30, 2011, in response to a Freedom of Information Act request, the NRC placed a large number of documents relating to the Fukushima accident onto the ADAMS system.¹⁹ They include a March 25, 2011, email from Elmo Collins, Regional Administrator in NRC’s Region IV, to Linda Howell, as he prepared to leave for Japan. The subject line is “Japan,” and it reads, in its entirety, as follows: “I’ll need to pick up some KI and make sure I have my dosimetry as needed – what dose meter would be good for me to take? Thanks, Elmo.”

Of course Mr. Collins provided himself with KI, and rightly so. NRC personnel are not reckless when it comes to their own safety or that of their children, nor should they be.²⁰ But if ever there is a nuclear catastrophe in this country, whether caused by terrorism or an accident, and Americans living more than 10 miles from a nuclear power plant discover that *their* children have been inadequately protected against radioactive iodine owing to the NRC’s unremitting, no-holds-barred battle to prevent or limit KI stockpiling – a battle that has included misrepresenting, *including to Congress*, the findings of a Congressionally mandated study of the issue by the National Academies of Science, and working to ensure that the sensible recommendations of the NAS were rejected by the President – the consequences would be devastating, not only for the affected children, but also for the NRC.

What would the country say when it learned that KI had been removed from the Strategic National Stockpile, with the result that we are less well prepared to cope with the medical effects of a nuclear disaster than we were a few years ago? The NRC Chairman and Commissioners would probably find themselves having to explain their actions not only to Congressional committees but to grand juries. Under those circumstances, it is hard to imagine that the Nuclear Regulatory Commission would even survive for long, at least under that name.²¹ More likely, it would be abolished and replaced by some new regulatory body, as is currently happening in Japan.²²

Press reports indicate that radioiodine from Fukushima has turned up in air, water, and foodstuffs far from the damaged nuclear plants.²³ To continue to insist that KI stockpiling in this country be limited to a 10 mile radius around nuclear plants, and then only in states which request the drug, would be irresponsible beyond measure. The sooner the NRC faces up to this reality, the better, and not only for the American public, but also for its own sake. The Task Force should be told to address the KI issue thoroughly and promptly. In addition, the Inspector General should be asked to investigate the staff's handling of KI matters in recent years, including, but not limited to, the appearance of NUREG-1633 in the Marburger decision, the accuracy of the 2005 Kane letter to HHS, and the 2006 response to Senator Voinovich.²⁴

What I have described in this memorandum are facts as I understand them, as informed by nearly 30 years of observing the NRC's handling of the KI issue. It has been prepared in a spirit of trying to be of service both to the American people and to the NRC. In this case, dealing as it does with a medication, a quotation from Gotthold Lessing's 18th Century play "Nathan the Wise" is particularly apposite: "It is medicine, not poison, that I am handing you."

/s/

Peter Crane, Counsel for Special Projects (retired)

cc: Senator George Voinovich
Senator Johnny Isakson
Senator Thomas Carper
Representative Ed Markey
Representative Henry Waxman

Appendix -- My Service with NRC

For the benefit of Commissioners who do not know me, I joined the NRC in early 1975, when it was 10 weeks old, and spent 27 years serving the agency in various capacities. I had been hired as a legal assistant, GS-12, by Commissioner (later Chairman) Marcus A. Rowden. In those days, it was standard for Commissioners to have two assistants, one technical and one legal, and two secretaries. (The Chairman at the time had a staff of seven: one technical assistant for reactors, another for materials, a legal assistant,

an executive assistant, and three secretaries.) For the first year I was there, however, Commissioner Rowden made do with just a single assistant, me, until he added Hugh Thompson as a technical assistant in 1976.

I moved to the Office of General Counsel on the expiration of Chairman Rowden's term in 1977. Over the next 24 years (there was a one-year break in service, during which I was an administrative judge in Micronesia), I defended the NRC's actions in court with vigor and conviction. My first case, in the D.C. Circuit, involved the Mark II containment; my last, in the Sixth Circuit, resulted in a decision upholding the NRC regulatory scheme for approving the design of dry casks for spent fuel storage.

In the Ninth Circuit, some 30 years ago, I briefed, argued, and won a case defending the adequacy of the fixes that the NRC ordered in Babcock and Wilcox reactors after the Three Mile Island accident. At one point in the 1980's, I served very briefly as Acting General Counsel, in which capacity I called on the Solicitor General, the late Rex Lee, to ask him to take to the Supreme Court a case which I had briefed, argued, and lost in the D.C. Circuit. It involved the NRC's refusal to treat the "psychological impacts" of the resumed operation of Three Mile Island Unit 1 as environmental impacts within the meaning of the National Environmental Policy Act. Lee was fully in accord. He took the case to the Supreme Court, which reversed the D.C. Circuit and upheld the NRC position on a unanimous vote.

I was made Counsel for Special Projects in the mid-1980's and retired with that title in 1999. In 2001, I was brought on as a contractor to write speeches for then Chairman Meserve, and I continued in that function under Chairman Diaz until 2005. During my long tenure with NRC, I was privileged, in addition to my usual legal duties, to write speeches, testimony, and/or personal statements for Chairmen Rowden, Palladino, Hendrie, Zech, Jackson, Selin, Meserve, and Diaz, including Senate confirmation testimony for three of those just named.

While at NRC, I was invited to speak at a United Nations conference in Moscow in 1997 on responding to man-made disasters. In 1998, in my private capacity, I was a speaker at a conference at Cambridge University in England on the U.S. Government's handling of the KI issue. The conference was co-sponsored by the university, the European Commission, the National Cancer Institute, and DOE. The paper I presented may be found in published form in the 1999 volume *Radiation and Thyroid Cancer*, edited by G. Thomas, A. Karaoglou, and E. D. Williams.